Amendment Dated August 6, 2007 Reply to Office Action of June 19, 2007

<u>Amendments to the Claims:</u> This listing of claims will replace all prior versions, and listings, of claims in the application

Listing of Claims:

- 1. (Previously Presented) A compounding control method for use with at least one pharmaceutical compounding device having an associated plurality of source solutions and a mixture receptacle to prepare a compounded mixture, the method comprising:
 - a) scanning a bar code of said installed plurality of source solutions;
- b) scanning a bar code of respective ones of transfer tubing adapted to be coupled to said plurality of source solutions;
- c) comparing the scanned information of the installed plurality of source solutions and transfer tubing with an expected configuration;
- d) either permitting the operator to commence compounding if the comparison is valid or preventing the operator from compounding if the comparison is invalid;
 - e) determining respective expiration dates of said plurality of source solutions;
- f) at least one of providing a warning and preventing use of any of said plurality of source solutions based on said determination step e);
 - q) accepting mixture inputs for one or more of said plurality of source solutions; and
- h) urging at least a portion of at least one of said plurality of source solutions into said mixture receptacle based on said mixture inputs to form said compounded mixture.
- 2. (Currently Amended) A compounding control method for use with at least one pharmaceutical compounding device having an associated plurality of source solutions and a mixture receptacle to prepare a compounded mixture, the method comprising:
- a) determining whether said plurality of source solutions conform to a predetermined mounting order installation configuration on said compounding device;
- b) at least one of providing an alert to an operator and preventing compounding based on said determining step a);
 - c) determining respective expiration dates of said plurality of source solutions;
- d) at least one of providing a warning and preventing use of any of said plurality of source solutions based on said determination step c);

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e) accepting mixture inputs for one or more of said plurality of source solutions;

- f) determining a nutritional assessment of a patient;
- g) comparing said mixture inputs with said nutritional assessment;
- h) providing an output to a user based on said comparison; and
- i) urging at least a portion of at least one of said plurality of source solutions into said mixture receptacle based on said mixture inputs to form said compounded mixture.
- 3. (Currently Amended) A compounding control method for use with at least one pharmaceutical compounding device having an associated plurality of source solutions and a mixture receptacle to prepare a compounded mixture, the method comprising:
- a) determining whether said plurality of source solutions conform to a predetermined mounting order installation configuration on said compounding device;
- b) at least one of providing an alert to an operator and preventing compounding based on said determining step a);
 - c) determining respective expiration dates of said plurality of source solutions;
- d) at least one of providing a warning and preventing use of any of said plurality of source solutions based on said determination step c);
 - e) accepting mixture inputs for one or more of said plurality of source solutions;
- f) determining if a lipid source solution and a dextrose source solution one of immediately follow or immediately precede one another;
 - g) generating an alert to a user based on said determination;
- h) preventing further processing of the compounded mixture until at least one buffer source solution is selected to be provided between said lipid source solution and said dextrose source solution; and
- i) urging at least a portion of at least one of said plurality of source solutions into said mixture receptacle based on said mixture inputs to form said compounded mixture based on whether said determination step h) is satisfied if necessary.
- 4. (Original) The method according to claim 1, further comprising the step of generating a bar coded label based at least in part on a composition of the compounded mixture in the mixture receptacle.

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5. (Currently Amended) A compounding control method for use with at least one pharmaceutical compounding device having an associated plurality of source solutions and a mixture receptacle to prepare a compounded mixture, the method comprising:

- a) determining whether said plurality of source solutions conform to a predetermined mounting orderconfiguration;
- b) at least one of providing an alert to an operator and preventing compounding based on said determining step a);
 - c) determining respective expiration dates of said plurality of source solutions;
- d) at least one of providing a warning and preventing use of any of said plurality of source solutions based on said determination step c);
 - e) accepting mixture inputs for one or more of said plurality of source solutions;
- f) urging at least a portion of at least one of said plurality of source solutions into said mixture receptacle based on said mixture inputs to form said compounded mixture;
 and

selecting an infusion pump type for dispensing the compounded mixture prior to beginning compounding the compounded mixture.

- 6. (Previously Presented) A compounding control method for use with at least one pharmaceutical compounding device having an associated plurality of source solutions and a mixture receptacle to prepare a compounded mixture, the method comprising:
- a) determining whether said plurality of source solutions conform to a predetermined configuration;
- b) at least one of providing an alert to an operator and preventing compounding based on said determining step a);
 - c) determining respective expiration dates of said plurality of source solutions;
- d) at least one of providing a warning and preventing use of any of said plurality of source solutions based on said determination step c);
 - e) accepting mixture inputs for one or more of said plurality of source solutions;

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 f) urging at least a portion of at least one of said plurality of source solutions into said mixture receptacle based on said mixture inputs to form said compounded mixture;
 and

- g) selecting at least one of an infusion ramp-up time and a ramp-down time for dispensing the compounded mixture.
- 7. (Original) The method according to claim 1, wherein said determining step c) is based at least in part on a bar code scan of said source solution.
- 8. (Original) The method according to claim 1, wherein said urging step f) is based at least in part on a proportional-integral-derivative (PID) control of a pump element of said compounding device.
- (Original) The method according to claim 1, further comprising the steps of:
 receiving an input signal from a pump element of the compounding device indicative of pump motor speed error; and

sending an output correction signal to said pump element to compensate for said motor speed error.

- (Original) The method according to claim 9, further comprising the steps of: determining a direction of rotation of at least a portion of said pump element; comparing said direction to a desired direction of rotation; and setting an alarm condition based on said comparison.
- 11. (Previously Presented) A compounding control method for use with at least one pharmaceutical compounding device having an associated plurality of source solutions and a mixture receptacle to prepare a compounded mixture, the method comprising:
- a) determining whether said plurality of source solutions conform to a predetermined configuration on said compounding device;
- b) at least one of providing an alert to an operator and preventing compounding based on said determining step a);
 - c) determining respective expiration dates of said plurality of source solutions;
- d) at least one of providing a warning and preventing use of any of said plurality of source solutions based on said determination step c);

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- e) accepting mixture inputs for one or more of said plurality of source solutions;
- f) urging at least a portion of at least one of said plurality of source solutions into said mixture receptacle based on said mixture inputs to form said compounded mixture;
- g) determining a state of motion of a plurality of pump elements of said compounding device;
- h) generating a first alert signal if any of said plurality of pump elements are in a state of motion that should otherwise be stationary, said alert advising of a defective compounded mixture; and
- i) generating a second alert signal if any of said plurality of pump elements are in a stationary state that should otherwise be in motion.
- 12. (Previously Presented) The method according to claim 1, further comprising: determining if selection of said source solutions may form an insoluble precipitate; and
 - generating an alert signal based on said comparison.
- 13. (Previously Presented) The method according to claim 1, further comprising: generating a label comprising indicia indicative of attributes of said compounded mixture.
- 14. (Original) The method according to claim 1, wherein said mixture inputs are received via a touch screen display.
- 15. (Previously Presented) The method according to claim 14, further comprising selectively deactivating a tactile input of said touch screen display for a predetermined period to allow for cleaning of a surface of said touch screen display.
- 16. (Previously Presented) A compounding control method to prepare a compounded mixture for use with at least one pharmaceutical compounding device having an associated plurality of source solutions and a mixture receptacle, the method comprising:
- a) determining whether said plurality of source solutions conform to a predetermined configuration;
- b) at least one of providing an alert to an operator and preventing compounding based on said determining step a);

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c) determining respective expiration dates of said plurality of source solutions;

- d) at least one of providing a warning and preventing use of any of said plurality of source solutions based on said determination step c);
 - e) accepting mixture inputs for one or more of said plurality of source solutions;
- f) urging at least a portion of at least one of said plurality of source solutions into said mixture receptacle based on said mixture inputs to form said compounded mixture;
- g) advising a user of at least one of maintenance procedures and replacement of component parts of the compounder device;
 - h) receiving input from said user responsive to said advising step g); and
- i) preventing further processing of said compounded mixture until said input from said user indicates compliance with said advising step g).
- 17. (Previously Presented) A compounding control method for use with at least one pharmaceutical compounding device having an associated plurality of source solutions and a mixture receptacle to prepare a compounded mixture, the method comprising:
- a) determining whether said plurality of source solutions conform to a predetermined configuration;
- b) at least one of providing an alert to an operator and preventing compounding based on said determining step a);
 - c) determining respective expiration dates of said plurality of source solutions;
- d) at least one of providing a warning and preventing use of any of said plurality of source solutions based on said determination step c);
 - e) accepting mixture inputs for one or more of said plurality of source solutions;
- f) urging at least a portion of at least one of said plurality of source solutions into said mixture receptacle based on said mixture inputs to form said compounded mixture;
 - a) providing the user with an inventory of mixture receptacles for selection;
 - h) receiving a input from the user for selecting a desired mixture receptacle;
- i) comparing said selection with a volume of said desired compounded mixture based on said mixture inputs of step e); and

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compounded mixture;

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j) generating an alert to said user if said volume of said desired compounded mixture exceeds a volume of said selected mixture receptacle and preventing further processing until an alternate selection of a mixture receptacle is made that will accommodate said compounded mixture.

18. (Previously Presented) The method according to claim 1, further comprising: determining if a plurality of said compounded mixture are to be prepared; determining if any of a plurality of additive solutions are to be part of said

determining if any of said plurality of additive solutions may be pooled into a pooled additive solution;

urging at least one of said plurality of additive solutions into a pooled additive solution container; and

designating said pooled additive solution as a further source solution for preparation of said compounded mixture.

19. (Previously Presented) The method according to claim 1, wherein the urging step further comprises:

determining if a container of any of said source solutions dictate a low flow rate; and setting said urging for said source solution to have a reduced upper speed limit based on said determining step in order to prevent a false flow rate alarm condition.

- 20. (Currently Amended) A compounding control method for use with at least one pharmaceutical compounding device having an associated plurality of source solutions and a mixture receptacle to prepare a compounded mixture, the method comprising:
- a) determining whether said plurality of source solutions conform to a predetermined mounting order installation configuration on said compounding device;
- b) at least one of providing an alert to an operator and preventing compounding based on said determining step a);
 - c) determining respective expiration dates of said plurality of source solutions;
- d) preventing use of any of said plurality of source solutions based on said determination step c);

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- e) determining if a plurality of compounded mixtures are to be prepared;
- f) determining if any of a plurality of additive solutions are to be part of said compounded mixture;
- g) determining if any of said plurality of additive solutions may be pooled into a pooled additive solution;
- h) urging at least one of said plurality of additive solutions into a pooled additive solution container based on said determining step g);
 - i) designating said pooled additive solution as a further source solution;
 - j) accepting mixture inputs for one or more of said plurality of source solutions; and
- k) urging at least a portion of at least one of said plurality of source solutions into said mixture receptacle based on said mixture inputs to form said compounded mixture.
- 21. (Currently Amended) A compounding control system for use with at least one pharmaceutical compounding device having an associated plurality of source solutions and a mixture receptacle for preparing a compounded mixture, the system comprising:

first determining means for determining whether said plurality of source solutions conform to a predetermined <u>mounting orderconfiguration</u>;

means for generating at least one of an alert to an operator and preventing compounding based on an output of said first determining means;

second determining means for determining respective expiration dates of said plurality of source solutions;

means for preventing use of any of said plurality of source solutions based on an output of said second determining means;

input means accepting mixture inputs for one or more of said plurality of source solutions;

pumping means for pumping at least a portion of at least one of said plurality of source solutions into said mixture receptacle based on said mixture inputs to form said compounded mixture; and

selection means for selecting an infusion pump type for dispensing the compounded mixture prior to beginning compounding the compounded mixture.